

**REMARKS**

Claim 52 is canceled. Claim 35, 38, 47, 48, 49, 50, 51, 52, and 53 are currently amended. Claim 70 is new. Claims 1-7, 11-26, 32-38, 40, 46-54, 60-67, and 70 are currently pending. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

**I. RESTRICTION/ELECTIONS**

The Examiner has withdrawn additional claims (Claims 8, 9, 27, 30, 31, 41-44, 55, 58, 59, 68, and 69), asserting that they belong to a non-elected species. Applicants respectfully traverse the withdrawal and believe they are entitled to those claims as part of the elected species. In an effort to facilitate the prosecution of this application towards allowance, the above claims have been listed as withdrawn. They will be reinstated upon allowance of a generic claim.

**II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

A. The Examiner has rejected claims 1-7, 11-15, 33-36, 38, 40, 46, 53, 54 and 67 under 35 U.S.C. § 102(b) as being anticipated by Mazzocchi US Patent 6,506,204 (hereinafter Mazzocchi).

According to the MPEP 2131, “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” The Examiner asserts that “Mazzocchi discloses an implant comprising an inflatable partitioning element (60) having an outer periphery with a proximal face (70), at least one anchoring element (72), a distal face (82) and a hub (15).” See Office Action, Page 2. Applicants respectfully traverse the above rejection as Mazzocchi does not disclose every limitation of the claimed invention.

For example, independent claims 1, 21, 33, 53, and 67 all recite a device for treating a patient’s heart comprising “an *inflatable partitioning element*” or “*an inflatable partitioning means*.” See Claims 1, 21, 33, 53, and 67. Mazzocchi does not disclose an *inflatable partitioning element* or an *inflatable partitioning means*. Instead, Mazzocchi discusses an *expandable* device. For example, Mazzocchi provides that “[s]uch devices of the invention are formed of a metal fabric and have an *expanded* configuration and a collapsed configuration.” See Mazzocchi, Col. 3,

lines 59-60. Thus, there are only two states for Mazzocchi's device, collapsed for delivery and fully expanded to a preselected size and configuration. In contrast to Mazzocchi, Applicants' claimed invention is inflatable and thus infinitely adjustable. The inflatable feature allows for decisions to be made as to the extent of inflation during the course of installation within the ventricle. Therefore the limitation of an *inflatable* partitioning element as in Claims 1, 21, 33, 52, and 67 is not disclosed by Mazzocchi.

As all of the claim limitations of independent Claims 1, 21, 33, 52, and 67 have not been disclosed by Mazzocchi, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) of Claims 1-7, 11-15, 33-36, 38, 40, 46, 53, 54, and 67.

B. The Examiner has rejected claims 1-3, 5-7, 15-26, 32, 53, 54, 60 and 61 under 35 U.S.C. § 102(e) as being anticipated by Van Tassel et al. U.S. Patent No. 6,652,555 (hereinafter Van Tassel). The Examiner asserts that "Van Tassel discloses an inflatable partitioning element (see Fig. 14) having an interior configured to receive inflation fluid, a distally extending supporting element (402), a hub (408) and a valve (426)". See Office Action, Page 3. Applicants respectfully traverse the rejection as Van Tassel does not disclose each and every element of the claims.

Independent Claims 1, 21, and 53 recite a device for treating a patient's heart comprising "an *inflatable partitioning element*," or "an "*inflatable partitioning means*". See Claims 1, 21, and 53. Van Tassel does not disclose an inflatable partitioning element or means. Instead, Van Tassel discloses a membrane that is "expanded for positioning across or over the ostium" of the atrial appendage. See Van Tassel, Col. 2, lines 12-13. Such an expandable membrane can be secured by a "balloon structure 402 [which] expands within the atrial appendage 13 and secures the membrane 40 in position". See Van Tassel, Col. 10, lines 36-39. Thus, the only inflatable portion of the device, the balloon structure 402, is not a partitioning element. Thus, Van Tassel does not disclose each and every limitation of Claims 1, 21, and 53 and therefore does not anticipate Claims 1, 21, and 53.

Since Van Tassel does not anticipate Claims 1, 21, and 53, the above rejection cannot stand. Based on the foregoing, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 102(e) of Claims 1-3, 5-7, 15-26, 32, 53, 54, 60 and 61.

### **III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)**

The Examiner has rejected Claims 21 and 37 under 35 U.S.C. § 103(a) as being unpatentable over Mazzocchi in view of Lichtenstein U.S. Patent Pub. 2005/0015109 (hereinafter Lichtenstein). According to the Examiner, “it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surface of the proximal end of the Mazzocchi reference by adding hooks around the surface in order to secure the implant into parts of the human body.” See Office Action, Page 4.

Applicants respectfully traverse the above rejection as the Examiner has failed to establish a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness the Examiner must show that Mazzocchi and Lichtenstein (independently or in combination) teach or suggest all of the limitations of Claims 21 and 37. The above showing has not been made.

Independent Claim 21 recites a device comprising “*an inflatable partitioning element*.” See Claim 21. As discussed above, Mazzocchi does not teach or suggest *an inflatable* partitioning element. Lichtenstein does not cure the above defect as it also fails to teach or suggest *an inflatable* partitioning element. Instead Lichtenstein teaches an expandable device. Therefore, Mazzocchi and Lichtenstein (independently or in combination) do not teach or suggest all the limitations of Claim 21, and a *prima facie* case of obviousness has not been established. Based on the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 103(a) of independent Claim 21.

Claim 37 recites the limitations of the device according to Claim 36 wherein the anchoring means comprise a hook or a barb. Since Claim 37 depends on Claims 33 and 36, all of the claim limitations of Claim 33 and 36 are incorporated in Claim 37. As Claim 33 recites the limitation of an inflatable partitioning means, Mazzocchi and Lichtenstein (independently or in combination) do not teach or suggest all the limitations of Claim 37. Therefore, the above rejection cannot stand. Based on the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 103(a) of Claims 21 and 37.

### CONCLUSION

For the foregoing reasons, Applicant requests the Examiner allow claims 1-7, 11-26, 32-40, 46-54, and 60-67 and advance the application to issuance.

### FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 33108-703.201).

Respectfully submitted,

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